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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/895,463
	Filing Date	June 29, 2001
	First Named Inventor	A.K. Gunnar Aberg
	Group Art Unit	2122
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	559P019

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 18- References
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Kevin S. Lemack Niels & Lemack
Signature	
Date	September 14, 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : A.K. Gunnar Aberg  
Serial No. : 09/895,463  
Filed : June 29, 2001  
For : TOLTERODINE METABOLITES  
Examiner : Not yet assigned  
Art Unit : 2122  
Attorney  
Docket No. : 559P019

Assistant Commissioner of Patents and Trademarks  
Washington, D.C. 20231

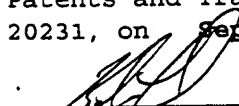
Sir:

INFORMATION DISCLOSURE STATEMENT


The Examiner is respectfully requested to consider the enclosed documents which are listed on the attached form PTO 1449.

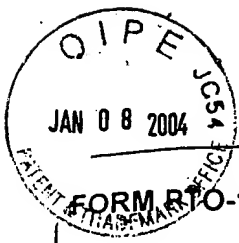
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Signature: Kevin S. Lemack  
Date: September 14, 2001

Respectfully submitted,

  
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FORM RTO-1449

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

ATTY. DOCKET NO.

559P019

SERIAL NO.

09/895,463

A.K. Gunnar Aberg

FILING DATE

June 29, 2001

GROUP

2122

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,236,956	8/1993	Sjogren et al.	514	617	
	AB	5,382,600	1/1995	Jonsson et al.	514	603	
	AC	5,532,278	7/1996	Aberg et al.	514	617	
	AD	5,559,269	9/1996	Johansson et al.	564	443	
	AE	5,677,346	10/1997	Aberg et al.	51	617	
	AF	5,686,464	11/1997	Johansson et al.	514	315	
	AG	5,736,577	4/1998	Aberg et al.	514	617	
	AH	5,922,914	7/1999	Gage et al.	564	413	
	AI						
	AJ						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BA	0 325 571	7/1989	Europe				
	BB	0 667 852	8/1995	Europe				

## OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

(1) Nilvebrant et al.: Tolterodine - a new bladder-selective antimuscarinic agent.  
Europ. J. Pharmacol. 1997, 327: 196-207

CA

--- There are over 20,000 publications on the drug tolterodine. This publication by Nilvebrant et al. is one of the more comprehensive reviews of the pharmacological activities of tolterodine, written by the people that invented tolterodine.

(2) Nilvebrant et al.: Antimuscarinic potency and bladder selectivity of PNU-200577, a major metabolite of tolterodine. Pharmacol Toxicol, 1997, 81:169-172  
--- Describes 5-hydroxymethyl-tolterodine as a major metabolite of tolterodine

CB

(3) Brynne et al.: Pharmacokinetics and pharmacodynamics of tolterodine in man: a new drug for the treatment of urinary bladder overactivity. Int J Clin Pharmacol Ther 1997, 35: 287-295

CC

--- Demonstrates that tolterodine undergoes extensive and variable hepatic first-pass metabolism. Both N-dealkylation and oxidation of the 5-methyl group are mentioned (see page 293, Discussion)

(4) Andersson et al.: Biotransformation of tolterodine, a new muscarinic antagonist, in mice, rats, and dogs. Drug Metab Dispos. 1998, 26:528-535  
---The in vivo metabolism of tolterodine in mice, rats and dogs is described. Both dealkylated and 5-HM-oxidized metabolites are described

CD

(5) Gillberg, P-G, Sundquist, S.: Pharmacological profile of DDO1 and desethyloxybutynin (DEOB). J. Urol 1997, 157: 81 p (Abstract)

\_\_\_\_\_ CE

--- This publication concerns the antimuscarinic activity of the tolterodine metabolite 5-hydroxymethyl-tolterodine (here called DDO1) and an active metabolite of the competing drug oxybutynin (desethyl-oxybutynin, here called DEOB)

(6) Pharmacia-Upjohn: Prescribing Information for Detrol (tolterodine tablets) <http://www.detrol.com.pi/index.htm>

\_\_\_\_\_ CF

--- This is the official drug product information from the manufacturer. The metabolism of tolterodine is described on pages 1 and 2. On page 6 there is a discussion of the risk for QT prolongation. A prolongation of 10 - 20% in the dog is called a "slight prolongation" although it is well known that a prolongation of 25 - 30% is fatal.

(7) Postlind et al.: Tolterodine, a new muscarinic receptor antagonist, is metabolized by cytochromes P450 2D6 and 3A in human liver microsomes. Drug Metab Dispos 1998, 26: 289-293).

\_\_\_\_\_ CG

--- This publication describes how the metabolites of tolterodine (by specific liver enzymes). Both the formation of 5-hydroxymethyl-tolterodine and the secondary amine metabolite are described in detail.

(8) Stahl et al.: Urodynamic and other effects Of Tolterodine... Neurourol Urodyn 1995, 14: 647-655

\_\_\_\_\_ CH

--- This publication deals with clinical pharmacological activities and is part of the core documentation for tolterodine,

EXAMINER	DATE CONSIDERED
EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance <i>and</i> not considered. Include copy of this form with next communication to applicant.	

\*=English Abstract

SR=Cited in Search Report